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09

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/531,369 03/21/00 WILLIAMSON M 07334-122001

HM12/0829

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EXAMINER

CANELLA, K

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED:

08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/531,369	Applicant(s) Williamson
	Examiner Karen Canella	Art Unit 1642



*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1)  Responsive to communication(s) filed on \_\_\_\_\_

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

4)  Claim(s) 1-20 is/are pending in the applica

4a) Of the above, claim(s) 4-20 is/are withdrawn from considera

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-3 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirem

#### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____	20) <input type="checkbox"/> Other: _____

***Response to Amendment***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claim 1 has been amended. Claims 1-20 are pending. Claims 4-20, drawn to non-elected inventions, are withdrawn from consideration. Claims 1-3 are under consideration.

***Claim Rejections Maintained***

3. The rejection of claims 1-3 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is maintained for reasons of record. Claim 1 has been amended to recite "candidate modulator" in place of "modulates" in order to obviate this rejection. Applicant argues that the objections raised by the examiner are not relevant to the instant claims as drawn to screening methods that can be used to determine whether a test compound is a candidate modulator of drug resistance in a cell. This has been considered but not found persuasive for the reasons set forth in the office action of Paper No. 2. The following explanation is set forth in order to clarify the reasons of record. It is well known in the art that the MDR phenotype, as exemplified by doxorubicin resistance, is often mediated by the overexpression of the p-gp efflux pump (Sadasivan et al, Cancer Letters, 1991, Vol. 57, pp. 165-171). Compounds have been discovered which interact directly with this transmembrane pump (Berger et al, Journal of Medicinal Chemistry, 1999, Vol. 42, pp. 2145-2161, abstract). Treatment with said compounds modulates the drug resistance of a cell overexpressing p-gp by binding directly to the components of the p-gp pump, not by altering the expression level of the p-gp protein in the cell. The instant specification provides no evidence that disabling of the p-gp pump would result in an altered level of MDA-9 expression as the level of expression of p-gp would not have been altered. One of skill in the art would be subject to undue experimentation, without reasonable expectation of success ,in order establish that determination of MDA-9 expression was correlated with the presence or absence of a candidate modulator of drug resistance.

*Conclusion*

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.  
Patent Examiner, Group 1642

August 27, 2001



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